

Serial No. 09/908,950 filed 7/19/01  
Response of 6/26/09 to Office Action of 10/16/08

### Remarks

Receipt is acknowledged of the Office Action of October 16, 2008 in the above-captioned matter. Reconsideration of all of the rejections and all available extensions of the time provided for response are respectfully requested. The Commissioner is authorized to debit all amounts required from Deposit Account No. 50-1604.

#### Rejections Under 35 U.S.C. §103

In the Office Action, the pending claims were also rejected under 35 U.S.C. §103(a) based on Skouv (U.S. Patent No. 6,303,315) in view of Gerhart et al., or Skouv in view of Gerhart and Van Ness. Reconsideration of the rejections is respectfully requested.

In the Office Action, it was submitted that Skouv teaches the incubation of a first component comprising RNA extracted from a sample, said RNA comprising a capture sequence and a target specific sequence, based on citations to col. 10 lines 37-41, col. 7 lines 44-56, and col. 3 line 32-61. However, it is respectfully submitted that none of those citations discuss the claimed capture sequence and target specific sequence of the invention.

For example, the citation at column 10 merely discusses that “[i]n regard to the isolation of RNA ... a chaotropic agent, such as a salt of isothiocyanate ... does not provide for the complete disruption of protein and nucleic acid interactions, and thus prevents optimal hybridisation”. Thus, this citation does not discuss either the capture sequence or target specific sequence.

Column 3 discusses the meaning of a “target nucleic acid”. For example, it discusses that

Serial No. 09/908,950 filed 7/19/01  
Response of 6/26/09 to Office Action of 10/16/08

the “target nucleic acid” is the nucleotide sequence whose presence is of interest and whose presence or absence is to be detected in the hybridization array, and the characteristics of such targets.

The citation at column 7 then discusses that “[s]equences suitable for capturing or signal nucleic acids for use in hybridisation arrays can be obtained from the entire sequence or portions thereof of an organism’s genome, from messenger RNA, or from cDNA obtained by reverse transcription of messenger RNA” and goes on to refer to texts regarding methods for obtaining the nucleotide sequence from such obtained sequence, and sequence databases.

But as discussed several paragraphs above that citation (at col. 7 lines 1-10 of Skouv), the Skouv patent is referring to “capturing nucleic acids” which are covalently immobilized to a solid support and labelled “signal” nucleic acids in solution. *See*, col. 7 lines 1-3. The sample provides the target nucleic acid. *See*, col. 7 lines 3 to 4. The “capturing” nucleic acid and the “signal” nucleic acid hybridise with the target nucleic acid to form a “sandwich” hybridisation complex. *See*, col. 7, lines 4-6.

Thus, the citations do not appear to teach a single RNA molecule which has both a target nucleotide sequence and a capture sequence in the same molecule, as required by claims 1, 19, 47 and 52.

Furthermore, the “capturing nucleic acids” in Skouv are immobilized to a support, which appears to be analogous, for example, to the probe nucleotide sequence hybridized to the microarray. This is a separate component from the RNA extracted from the target sample that is referred to in the pending claims, which RNA has both a target nucleotide sequence and a capture sequence.

Serial No. 09/908,950 filed 7/19/01  
Response of 6/26/09 to Office Action of 10/16/08

Accordingly, it is submitted that Skouv does not teach or suggest the claimed subject matter of the invention, whether alone or in view of Gerhart and Van Ness. Thus, it is submitted that the claimed subject matter is patentable over all of those references.

Furthermore, it is respectfully noted that a large number of rejections have been set forth in the application to date, all which have been demonstrated to be inapplicable and/or subsequently withdrawn. As the rejections and subsequent withdrawals show, the invention would not have been apparent to one of ordinary skill in the art based on the references of record. In fact, even after attempts at hindsight reconstruction of the invention, it still has not been shown to be taught or suggested in the art. It is submitted that further rejections would merely further demonstrate hindsight reconstruction of the invention. As shown by the prior rejections and their withdrawal, even after multiple searches and examinations of the claims, the subject matter of the invention has still not been shown to be taught or suggested by the references, even working backwards. It is therefore submitted that – working forwards – the invention would certainly not have been obvious to one of ordinary skill in the art at the time the invention was made.

In view thereof, it is submitted that the present invention is fully patentable and suitable for an allowance.

#### Double Patenting Rejections

In the application, the pending claims were provisionally rejected under the judicially created doctrine of obviousness-type double patenting based on co-pending Application No. 09/802,162.

Serial No. 09/908,950 filed 7/19/01  
Response of 6/26/09 to Office Action of 10/16/08

It was previously desired that the double patenting rejections be held in abeyance until the final form of the claims was established in this and/or the co-pending application. It is submitted that the claims in this application are currently in final form.

In the event that the Examiner agrees, reevaluation of the double patenting rejection is requested in view of the fact that the co-pending application is not directed to the use of a first component comprising RNA, and in fact, the stability problems associated with the use of RNA yet further demonstrate that use of RNA would have been and was non-obvious over the co-pending application at the time the present inventions were made. Reevaluation is also requested so that Applicant can determine whether or not a terminal disclaimer would be necessary.

In view of the foregoing, favorable action on the application is requested and believed fully warranted.

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Respectfully submitted,

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